

B<sup>3</sup>  
providing a wedge having a top surface positioned substantially under a toe and  
not extending under a first metatarsal, and a bottom surface; and  
elevating the toe to a predetermined angle of inclination using the wedge.

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**REMARKS**

Applicant thanks the Examiner for the careful review of this application. Please reconsider the application in view of the above amendments and the following remarks.

The instant invention relates to providing a wedge underneath a toe in order to provide for increased stability during ambulation. An advantage of the invention is the ease of application of the device, in that it may be disposed beneath the hallux as part of a sole in footwear, adhered to the sole after manufacture, or, in the absence of footwear, may be adhered to the hallux. Providing such a wedge beneath the hallux alleviates the pain of certain medical conditions while mitigating the effects of a number of degenerative conditions of the foot.

The Examiner rejected claims 1-3 and 10-13 under 35 U.S.C. § 102(e) as anticipated by Rothbart (6,092,314, "the '314 patent"). To the extent this rejection applies to the amended claims, Applicant respectfully traverses this rejection. The '314 patent discloses a device extending from the hallux through the posterior end of the first metatarsal (Col. 6, L. 30-37 and referencing Fig. 6). Furthermore, the device of the '314 patent is clearly intended to be a "foot support system" (Col. 6, L. 14) having an elongate bed "on which a portion of the foot rests" (Col. 6, L. 16). The '314 patent claims an "elongate bed" extending along "the first toe and first metatarsal" (Col. 10, L. 54 and Col. 12, L. 18). This language clearly indicates that the '314 patent differentiates the toe and first metatarsal and targets a portion of the foot, as apposed to the toe alone. Furthermore, this language differentiates the apparatus of the '314 patent from the instant device, which is intended to provide direct support only to the toe and immediate area. Claims 1 and 10, as amended, are limited to the toe region exclusive of the first metatarsal. Specifically, claims 1 and 10 include the "not extending under a first metatarsal" limitation. Rothbart '314 does not include this limitation. Therefore, it cannot anticipate the present invention. Claims 2, 3, 11, 12 and 13 depend from claims 1 and 10, and therefore, are not

anticipated by Rothbart '314 for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

With regard to the rejection of claims 4 and 5 under 35 U.S.C. § 103(a) as being obvious over the '314 patent. Applicant respectfully traverses this rejection to the extent it may apply to the amended claims, on the grounds that the '314 patent teaches away from the instant device. The focus of the instant device is direct support of the immediate toe area. The '314 patent is clearly targeted at an entire area of the foot "from the hallux 48 to the navicular 28" (Col. 6, L. 19-20). Furthermore, the '314 patent teaches that the back edge of the device may lie in a position posterior to the first metatarsal and more specifically, the back edge should extend into an area between the posterior end of the first metatarsal and the anterior end of the plantar surface of the calcaneus (Col. 6, L. 30-37). Thus, the '314 patent clearly teaches away from the instant device, which lies substantially under the toe. Claims 4 and 5 depend from claim 1 and include the limitation, "not extending under a first metatarsal." Therefore, the '314 patent cannot render claims 4 and 5 obvious. Accordingly, withdrawal of this rejection is respectfully requested.

With regards to the rejection of claims 7-9 and 15-23 under 35 U.S.C. § 103(a) as being unpatentable over the '314 patent in view of either Brock '927 or Jacoby '046, Applicant respectfully traverses this rejection to the extent that it may apply to the amended claims, on the grounds that the '314 patent teaches away from the instant device. The focus of the instant device is direct support of the immediate toe area. The '314 patent is clearly targeted at an entire area of the foot "from the hallux 48 to the navicular 28" (Col. 6, L. 19-20). Furthermore, the '314 patent teaches that the back edge of the device may lie in a position posterior to the first metatarsal and more specifically, the back edge should extend into an area between the posterior end of the first metatarsal and the anterior end of the plantar surface of the calcaneus (Col. 6, L. 30-37). Thus, the '314 patent clearly teaches away from the instant device, which lies substantially under the toe. Claims 7-9 and 15-23 depend from claims 1, 10, and 18, and include the limitation, "not extending under a first metatarsal." Therefore, the '314 patent cannot render

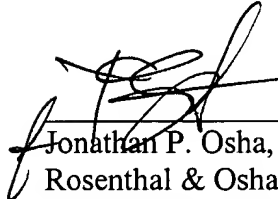
claims 7-9 and 15-23 obvious. Accordingly, withdrawal of this rejection is respectfully requested.

Regarding the rejection of claims 6 and 14 under 35 U.S.C. § 103(a) as being unpatentable over the '314 patent in view of McMahon et al. (5,881,478), Applicant respectfully traverses this rejection, to the extent it may apply to the amended claims, on the grounds that the '314 patent reference teaches away from the instant device. The focus of the instant device is direct support of the immediate toe area. The '314 patent is targeted at an entire area of the foot "from the hallux 48 to the navicular 28" (Col. 6, L. 19-20). Furthermore, the '314 patent teaches that the back edge of the device may lie in a position posterior to the first metatarsal and more specifically, the back edge should extend into an area between the posterior end of the first metatarsal and the anterior end of the plantar surface of the calcaneus (Col. 6, L. 30-37). Thus, the '314 patent teaches away from the instant device, which lies substantially under the toe. Claims 6 and 14 depend from claims 1 and 10 respectively and include the limitation "not extending under a first metatarsal." Therefore, the '314 patent cannot render claims 6 and 14 obvious. Accordingly, withdrawal of this rejection is respectfully requested.

Applicant believes this reply to be fully responsive to all outstanding issues and place this application in condition for allowance. If this belief is incorrect, or other issues arise, please do not hesitate to contact the undersigned or his associates at the telephone number listed below. Applicant wishes to thank the Examiner for her thorough review of the application. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 09166.002001).

Respectfully submitted,

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 #45,079  
Jonathan P. Osha, Reg. No. 33,986  
Rosenthal & Osha L.L.P.  
One Houston Center, Suite 2800  
1221 McKinney Street  
Houston, TX 77010  
Telephone: (713) 228-8600  
Facsimile: (713) 228-8778

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Appendix A: Marked-up Copy of the Claims

9. An orthopedic appliance, comprising a wedge for placement under a toe and not extending under a first metatarsal, the wedge having a top surface adapted to support the toe and a [lower] bottom surface, wherein an angle of inclination between the top surface and the bottom surface of the wedge is between 1 and 60 degrees.
10. An apparatus for orthopedic treatment, comprising:  
a top surface adapted to support a toe and not extending under a first metatarsal;  
a bottom surface; and  
a support which maintains a toe at an angle of inclination between the top surface and the bottom surface.
18. A method for improving stability of a foot during ambulation, comprising:  
providing a wedge having a top surface positioned substantially under a toe and not extending under a first metatarsal, and a bottom surface; and  
elevating [a] the toe to a predetermined angle of inclination using the wedge.

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